



*Item 431-J-15*

## Cooperative Research and Development Agreement With Spiral Biotech, Incorporated

### *The Development and Utilization of Automated and Semi-Automated Microbial Mutagenicity Assays*

#### Participants

This Cooperative Research and Development Agreement (CRADA) brings together Spiral Biotech Inc., (formerly Spiral System Instruments, Inc.) and the U.S. Environmental Protection Agency's (EPA) Health Effects Research Laboratory (HERL) in Research Triangle Park, North Carolina.

#### Purpose

This CRADA was developed for HERL to improve the overall automation of bacterial mutagenicity testing using instrumentation designed and manufactured by Spiral Biotech, Inc.

#### Background

HERL conducts research associated with the detection and identification of substances that may induce genetic damage. Several biological test systems have been developed over the past two decades to evaluate genotoxicity, including the well-known Salmonella mutagenicity assay. Due to its widespread and routine usage, there are increasing demands to automate the Salmonella assay. It is used in nearly 3000 laboratories worldwide.



Autoplate spiral plater

#### Results

This CRADA is ongoing, and to date, the automation of the Salmonella assay has reduced costs and man-hour efforts, conserved samples, and greatly simplified studies of chemical interactions. The agreement has allowed EPA to make recommendations for improvements to instrumentation and software, evaluation of modifications, and new developments of this instrument, and to improve overall the automation of bacterial mutagenicity testing.

A new plater model was recently designed by Spiral Biotech Inc., incorporating innovations suggested by HERL. Its release to the market represents a considerable advance over previous automation technology. Improvements have also been made, with guidance from HERL, to the computerized data management system; analysis capabilities have been enlarged and additional statistical applications are now possible. Finally, workshops have been conducted by HERL to provide users of this new technology with information and training. This agreement has also allowed Spiral Biotech Inc., to use the data generated by HERL to guide modifications to instruments and software.

This is one of more than 50 cooperative research and development agreements EPA has with various U.S. businesses, consortiums, trade associations, academic institutions and state and local governments under the Federal Technology Transfer Act of 1986. These agreements serve as a mechanism for EPA to work with private industry to develop new pollution prevention and control technologies and efficiently bring them into the marketplace.

#### Contacts

**Sam Schalkowsky**  
Chief Executive Officer  
Spiral Biotech, Inc.  
7830 Old Georgetown Road  
Bethesda, MD 20814  
Phone: (301) 657-1620  
FAX: (301) 657-5036



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**Virginia Stewart Houk**

Project Manager

Genetic Toxicology Division

U.S. EPA/HERL (MD-68A)

Research Triangle Park, NC 27711

Phone: (919) 541-2815

FAX: (919) 541-0968

**Dr. Larry Claxton**

Acting Director

Genetic Toxicology Division

U.S. EPA/HERL (MD-68)

Research Triangle Park, NC 27711

Phone: (919) 541-2518

FAX: (919) 541-0694

**Ron Rogers**

Technology Transfer Coordinator

Research Support Division

U.S. EPA/HERL (MD-70)

Research Triangle Park, NC 27711

Phone: (919) 541-2370

FAX: (919) 541-5394

**Jane E. Ice**

Technology Transfer Specialist

U.S. EPA/ORD

Office of Science, Planning and

Regulatory Evaluation

26 W. Martin Luther King Drive

Cincinnati, OH 45268

Phone: (513) 569-7311

FAX: (513) 569-7132